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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,079	11/25/2003	Yasukazu Nakayama	053466-0363	5443
22428	7590	08/13/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/720,079	<b>Applicant(s)</b> NAKAYAMA ET AL.	
	<b>Examiner</b> Christopher R. Tate	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### DETAILED ACTION

Claims 1-4 of this reissue application have been presented and examined on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In newly recited claim 4, the phrase "vitamin C or derivative thereof" (line 8) encompasses the use of any and all vitamin C derivatives within the claimed method. However, the specification (including the areas Applicants particularly point to for support thereof - i.e., col 4, lines 45-49 and 59-67) fails to provide an adequate written description of this broadening embodiment. That is, the specification is drawn to and reasonably teaches a method of promoting collagen production in a fibroblast of a subject via administering a composition comprising the claimed active components, including the particular vitamin C's recited in col 4, lines 45-49 and 59-67 of the instant specification (as well as in amended claim 1). However, no support was found in the instant specification for the use of any and all vitamin C derivatives (which broadly read upon a vast array of potential components including fragments, molecules, and/or atoms thereof; as well as other non-disclosed, art-recognized vitamin C derivatives) within the disclosed/claimed method.

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Accordingly, this broader embodiment represents new matter. 35 U.S.C. states that no amendment shall introduce new matter into the disclosure (including the claims) of the invention. Applicant is required to cancel the new matter in the reply to this Office action, or to specifically point to adequate support within the instant specification for the above new matter limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rendered vague and indefinite by the ambiguous phrase "vitamin C or derivative thereof" (line 8). This phrase is not adequately defined, nor are its metes and bounds clearly delineated - e.g., outside the particular vitamin C's recited in col 4, lines 45-49 and 59-67 of the instant specification, "vitamin C or derivative thereof" broadly reads upon a vast array of potential components including small fragments, molecules and/or atoms thereof, none of which are deemed to suitably define the instantly disclosed vitamin C's.

It is suggested that claim 4 be canceled in response to this Office action to overcome this rejection.

***Reissue New Matter Rejection Under 35 USC § 251***

Claim 4 is rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is the broader embodiment limitations with respect to vitamin C derivatives, as set forth under the U.S.C. 112, first paragraph rejection above for the reasons discussed therein.

Please note that should an amendment be filed in response to this Office action, a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) in accordance with 37 CFR 1.175(b)(1) may be required before this reissue application can be allowed. However, receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome any potential rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

“Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.”

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

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As a formal matter, please note that the instant reissue application cannot be allowed until either the original ribboned copy of Patent No. 6,531,165 has been surrendered or a statement addressing the loss or inaccessibility of the original patent is submitted by Applicant (see MPEP § 1416).

Further, the references cited in the original patent (Patent No. 6,531,165) must be cited in the reissue application. Accordingly, an Information Disclosure Statement (Form PTO-1449) listing all the references cited on the original patent is requested.

### **Conclusion**

Claims 1-3 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'CR Tate', with a horizontal line underneath.

Christopher R. Tate  
Primary Examiner  
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